



Patent  
Attorney's Docket No. 028722-317

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Pere Santamaria

Application No.: 10/005,917

Filed: December 7, 2001

For: COMPOSITIONS AND METHODS USEFUL IN  
AVIDITY THERAPY

Group Art Unit: 1633

Examiner: Unassigned

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**INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- No additional fee for submission of an IDS is required.
- The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- Charge \$\_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- A check in the amount of \$\_\_\_\_\_ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(650) 622-2300

By:

Ping F. Hwung  
Registration No. 44,164

Date: April 15, 2002



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Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

1. Amrani et al. 2001. Expansion of the antigenic repertoire of a single T cell receptor upon T cell activation. *J. Immunol.* 167(2):655-66.
2. Amrani, A., J. Verdaguer, P. Serra, S. Tafuro, R. Tan, and P. Santamaria. 2000. Progression of autoimmune diabetes driven by avidity maturation of a T-cell population. *Nature*. 406:739.
3. Amrani, A., J. Verdaguer, B. Anderson, T. Utsugi, S. Bou, and P. Santamaria. 1999. Perforin-independent beta cell destruction by diabetogenic CD8<sup>+</sup> T lymphocytes in transgenic nonobese diabetic mice. *J. Clin. Invest.* 103:1201.

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Page 2

4. Anderson, B., B.-J. Park, J. Verdaguer, A. Amrani, and P. Santamaria. 1999. Dominant CD8<sup>+</sup> T-cell response against a single peptide/MHC complex in autoimmune diabetes. *Proc. Natl. Acad. Sci. USA* 96:9311.
5. Bendelac, A., C. Carnaud, C. Boitard, and J. F. Bach. 1987. Syngeneic transfer of autoimmune diabetes from diabetic NOD mice to healthy neonates. *J. Exp. Med.* 166:823.
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11. Haskins, K., and M. McDuffie. 1990. Acceleration of diabetes in young NOD mice with a CD4<sup>+</sup> islet-specific T cell clone. *Science* 249:1433.
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- 16. Kagi, D., B. Odermatt, P. Seiler, R. Zinkernagel, T. Mak, and H. Hengartner. 1997. Reduced incidence and delayed onset of diabetes in perforin-deficient nonobese diabetic mice. *J. Exp. Med.* 186:989.
- 17. Katz, J., C. Benoist, and D. Mathis. 1995. T helper cell subsets in insulin-dependent diabetes. *Science* 268:1185.
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- 20. Lo, D., C. Reilly, B. Scott, R. Liblau, H. McDevitt, and L. Burkly. 1993. Antigen-presenting cells in adoptively transferred and spontaneous autoimmune diabetes. *Eur. J. Immunol.* 23:1693.
- 21. McInerney, M., S. Rath, and C. Janeway. 1991. Exclusive expression of MHC class II proteins on CD45<sup>+</sup> cells in pancreatic islets of NOD mice. *Diabetes* 40:648.
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- 23. Nagata, M., P. Santamaria, T. Kawamura, T. Utsugi, and J.-W. Yoon. 1994. Evidence for the role of CD8<sup>+</sup> cytotoxic T cells in the destruction of pancreatic beta cells in NOD mice" *J. Immunology* 152:2042

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- 28. Schmidt, D., J. Verdaguer, N. Averill, and P. Santamaria. 1997. A mechanism for the major histocompatibility complex-linked resistance to autoimmunity. *J. Exp. Med.* 186:1059.
- 29. Serreze, D., and E. Leiter. 1994. Genetic and pathogenic basis of autoimmune diabetes in NOD mice. *Curr. Opin. Immunol.* 6:900.
- 30. Serreze, D., E. Leiter, G. Christianson, D. Greiner, and D. Roopenian. 1994. Major histocompatibility complex class I-deficient NOD.b1m<sup>null</sup> mice are diabetes and insulitis resistant. *Diabetes* 43:505.
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Page 6

These documents are being submitted before a first Office Action on the merits, therefore no fee is required under 37 C.F.R. § 1.97(b). In the event an Office Action is mailed by the United States Patent and Trademark Office prior to receipt of this Information Disclosure Statement, the Commissioner is authorized to debit Deposit Account 02-4800 for the fee required by 37 C.F.R. §1.17(p).

By citing the above references, Applicants do not acquiesce or admit that any of these documents are "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:   
Ping F. Hwung  
Registration No. 44,164  
Attorney for Applicants  
Redwood Shores, CA Office  
(650)-622-2300

P.O. Box 1404  
Alexandria, Virginia 22313-1404

Date: April 15, 2002

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SHEET 1 OF 3

Substitute for form 1449A/PTO

ATTORNEY'S DKT NO.  
028722-317APPLICATION NO.  
10/005,917

APPLICANT

Pere Santamaria

FILING DATE

December 7, 2001

GROUP

1633

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## U.S. PATENT DOCUMENTS

Examiner Initials	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)
	Number	Kind Code (if known)		

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Foreign Patent Document		Country	Date of Publication (MM-DD-YYYY)	Translation Yes <input type="checkbox"/> no <input type="checkbox"/>
	Number	Kind Code (if known)			

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	Amrani et al. 2001. Expansion of the antigenic repertoire of a single T cell receptor upon T cell activation. <i>J. Immunol.</i> 167(2):655-66.				
	Amrani, A., J. Verdaguer, P. Serra, S. Tafuro, R. Tan, and P. Santamaria. 2000. Progression of autoimmune diabetes driven by avidity maturation of a T-cell population. <i>Nature</i> . 406:739.				
	Amrani, A., J. Verdaguer, B. Anderson, T. Utsugi, S. Bou, and P. Santamaria. 1999. Perforin-independent beta cell destruction by diabetogenic CD8 <sup>+</sup> T lymphocytes in transgenic nonobese diabetic mice. <i>J. Clin. Invest.</i> 103:1201.				
	Anderson, B., B.-J. Park, J. Verdaguer, A. Amrani, and P. Santamaria. 1999. Dominant CD8 <sup>+</sup> T-cell response against a single peptide/MHC complex in autoimmune diabetes. <i>Proc. Natl. Acad. Sci. USA</i> 96:9311.				
	Bendelac, A., C. Carnaud, C. Boitard, and J. F. Bach. 1987. Syngeneic transfer of autoimmune diabetes from diabetic NOD mice to healthy neonates. <i>J. Exp. Med.</i> 166:823.				
	Bradley, B., K. Haskins, F. L. Rosa, and K. Lafferty. 1992. CD8 T cells are not required for islet destruction induced by a CD4 <sup>+</sup> islet-specific T-cell clone. <i>Diabetes</i> 41:1603.				
	Christianson, S., L. Shultz, and E. Leiter. 1993. Adoptive transfer of diabetes into immunodeficient NOD-scid/scid mice. Relative contributions of CD4 <sup>+</sup> and CD8 <sup>+</sup> T-cells from diabetic versus prediabetic NOD.NON-thy-1a donors. <i>Diabetes</i> 42:44.				
	Daniel, D., R. Gill, N. Schloot, and D. Wegmann. 1995. Epitope specificity, cytokine production profile and diabetogenic activity of insulin-specific T cell clones isolated from NOD mice. <i>Eur. J. Immunol.</i> 25:1056.				
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	Kagi, D., B. Odermatt, P. Seiler, R. Zinkernagel, T. Mak, and H. Hengartner. 1997. Reduced incidence and delayed onset of diabetes in perforin-deficient nonobese diabetic mice. <i>J. Exp. Med.</i> 186:989.				
Examiner Signature		Date Considered			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

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SHEET 2 OF 3

Substitute for form 1449A/PTO

ATTORNEY'S DKT NO.

028722-317

APPLICATION NO.

10/005,917

APPLICANT

Pere Santamaria

FILING DATE

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	Katz, J., C. Benoist, and D. Mathis. 1995. T helper cell subsets in insulin-dependent diabetes. <i>Science</i> 268:1185.				
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	Kay, T., J. Parker, L. Stephens, H. Thomas, and J. Allison. 1996. RIP-b2-microglobulin transgene expression restores insulitis, but not diabetes, in b2-microglobulin null nonobese diabetic mice. <i>J. Immunol.</i> 157:3688.				
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	Nagata, M., P. Santamaria, T. Kawamura, T. Utsugi, and J.-W. Yoon. 1994. Evidence for the role of CD8 <sup>+</sup> cytotoxic T cells in the destruction of pancreatic beta cells in NOD mice. <i>J. Immunology</i> 152:2042				
	Nagata, M., and J.-W. Yoon. 1992. Studies on autoimmunity for T cell-mediated beta cell destruction: distinct difference in the destruction of beta cells between CD4 <sup>+</sup> and CD8 <sup>+</sup> T cell clones derived from lymphocytes infiltrating the islets of NOD mice. <i>Diabetes</i> 41:998.				
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	Shimizu, J., O. Kanagawa, and E. Unanue. 1993. Presentation of beta cell antigens to CD4 <sup>+</sup> and CD8 <sup>+</sup> T cells of non-obese diabetic mice. <i>J. Immunol.</i> 151:1723.				
	Thivolet, C., A. Bendelac, P. Bedossa, J. F. Bach, and C. Carnaud. 1991. CD8 <sup>+</sup> T cell homing to the pancreas in the nonobese diabetic mouse is CD4 <sup>+</sup> T cell-dependent. <i>J. Immunol.</i> 146:85.				
	Tisch, R., and H. McDevitt. 1996. Insulin-dependent diabetes mellitus. <i>Cell</i> 85:291.				
Examiner Signature		Date Considered			

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SHEET 3 OF 3

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STATEMENT BY APPLICANTATTORNEY'S DKT No.  
028722-317APPLICATION NO.  
10/005,917APPLICANT  
Pere SantamariaFILING DATE  
December 7, 2001GROUP  
1633RECEIVE  
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## U.S. PATENT DOCUMENTS

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	Number	Kind Code (if known)		

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	Utsugi, T., J.-W. Yoon, B.-J. Park, M. Imamura, N. Averill, S. Kawazu, and P. Santamaria. 1996. MHC class I-restricted infiltration and destruction of pancreatic islets by NOD mouse-derived beta cell-cytotoxic CD8 <sup>+</sup> T-cell clones in vivo. <i>Diabetes</i> 45:1121.					
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